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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,017,927

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,017,927, which claims the human drug product VESIcare® (solifenacin succinate) and pharmaceutical compositions comprising VESIcare® (solifenacin succinate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,058 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,058 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 23, 2006, (71 Fed. Reg. 14708), would be 1,231 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (1325 - 266) + 702
	=	1,231days (3.4 years)

Since the regulatory review period began May 5, 1999, before the patent issued (January 25, 2000), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 5, 1999, to and including January 25, 2000, is 266 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,231 days, would extend the patent from December 27, 2015 to May 11, 2019, which is beyond the 14-year limit (the approval date is November 19, 2004, thus the 14 year limit is November 19, 2018). The period of extension is thus limited to 1,058 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, December 27, 2015, to and including November 19, 2018, or 1,058 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,017,927
Granted:	January 25, 2000
Original Expiration Date[1]:	December 27, 2015
Applicant:	Makoto Takeuchi, et al.
Owner of Record:	Astellas Pharma Inc.
Title:	Quinuclindine Derivatives and Medicinal Composition Thereof
Product Trade Name:	VESIcare® (solifenacin succinate)
Term Extended:	1,058 days
Expiration Date of Extension:	November 19, 2018

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

RE: VESIcare® (solifenacin succinate)
FDA Docket No.: 2005E-0235

Attention: Beverly Friedman

[1]Subject to the provisions of 35 U.S.C. § 41(b).